REMARKS

This Amendment is being submitted in response to the Office Action dated March 24, 2008 in the above-identified application. Concurrently with this Amendment, Applicants submit a Request for Continued Examination and a petition for a three-month extension of time for filing a response, along with the requisite fees and the authorization to charge our Deposit Account 50-0552 for any fee deficiencies. The time for filing a response to the March 24, 2008 Office Action is thereby extended to September 24, 2008.

Claims 4 and 7-13 were pending in the case. Claims 1 to 3, 5 and 6 were previously canceled. By this response, claims 7 to 9 and claims 11 to 13 have been canceled without prejudice. No new matter has been introduced by the amendments. Claims 4 and 10 are now pending and under examination.

In view of the amendments made herein and the remarks below, Applicants respectfully request reconsideration and withdrawal of the rejections and objections set forth in the March 24, 2008 Office Action.

REJECTIONS UNDER 35 USC §112, FIRST PARAGRAPH

In the Office Action, the Examiner maintained the rejection to claims 4 and 7-9, and claims 10 to 12, under 35 U.S.C. 112, first paragraph, for the reasons of record on pages 2 to 9 of the Office Action mailed 07/05/2007 as failing to comply with the written description requirement and as failing to reasonably provide enablement to one of skill in the art to make/use the invention commensurate in scope with the claims.

Claim 4 of the present invention recites: "A method of lowering the blood glucose level which comprises administering an effective dose of a growth hormone secretagogue receptor (GHS-R) antagonist to a patient of diabetes mellitus, wherein said GHS-R antagonist is selected from the group consisting of a ghrelin analog antagonist, [D-Lys-

3]-GHRP-6 and [D-Arg-1, D-Phe-5, D-Trp-7, 9, Leu-11] substance P."

The Office Action asserts that "the specification's general discussion of screening for analogues constitutes an invitation to experiment by trial and error." See Office Action, page 3, lines 20 and 21. However, the present invention confirms the effect of the two representative compounds as described in the working examples. The specification of the present invention also provides clear guidelines on how to screen for ghrelin analog antagonist (See, for example, page 8, lines 21-28). Such screening method is also described in paragraph [0063] to [0067] of Andersen, and thus those skilled in the art can identify ghrelin analog antagonist without undue experimentation.

The present specification also provides sufficient description regarding to ghrelin analog antagonist (See, for example, page 11, lines 8-14) and also provides description regarding a side chain (See, for example, page 11, lines 15 to bottom). Therefore, those skilled in the art would be able to prepare ghrelin analog antagonist based on the description of the present invention and screen them without undue experiment.

The claimed method using [D-Lys-3] –GHRP-6 and [D-Arg-1, D-Phe-5, D-Trp-7, 9, Leu-11] substance P are described and enabled by the specification, for example, page 23, line 18 to page 25, line 20. In addition, the specification fully supports the claimed methods using a ghrelin analog antagonist, which are described in detail on page 10, line 6 to page 12, line 6.

In view of the above, withdrawal of the rejection of independent claim 4 under 35 U.S.C. 112, first paragraph, is respectfully requested. As claim 10 is dependent on independent claim 4, withdrawal of the rejection of claim 10 under 35 U.S.C. 112, first paragraph, is also respectfully requested.

Claims 7 to 9, 11 and 12 have been canceled without prejudice by way of this Response, therefore, the outstanding rejections to claims 7 to 9, 11 and 12 are moot.

REJECTIONS UNDER 35 USC §102

Claims 4 and 7-13 were rejected under 35 U.S.C. 102(b) as being anticipated by Andersen et al. (US 2001/0020012 A1). Applicants respectfully traverse the rejections.

Claim 4 of the present invention recites: "A method of lowering the blood glucose level which comprises administering an effective dose of a growth hormone secretagogue receptor (GHS-R) antagonist to a patient of diabetes mellitus, wherein said GHS-R antagonist is selected from the group consisting of a ghrelin analog antagonist, [D-Lys-3]-GHRP-6 and [D-Arg-1, D-Phe-5, D-Trp-7, 9, Leu-11] substance P."

The Office Action admits that Andersen is silent upon lowering blood glucose. See Office Action, page 8, line 17. The Office Action then asserts that "the administration of a compound for the treatment of diabetes would inherently result in lowering blood glucose level as required by the claim 4", and that "it is well known in the prior art that diabetes mellitus is associated with continuous and pathologically elevated blood glucose concentration." See Office Action, page 8, lines 17 to 20.

The Applicant respectfully disagrees with the Examiner's position. The fact that diabetes mellitus is associated with elevated blood glucose concentration does not lead to a conclusion that a drug useful in the treatment of diabetes necessarily lowers blood glucose level. For example, International Patent Publication WO 01/87335, which was cited in the International Search Report, states that the administration of GHRP-2, which is a GHS-R agonist, increases fat mass and bone mass (See for example, page 19, lines 19-20), but plasma levels of insulin and glucose were not changed by the administration of GHRP-2 (See, for example, page 20, lines 6-11). Therefore, suppressing lipid anabolism does not translate into a rise in a blood glucose level. Thus, those skilled in the art would not correlate inactivation of GHS-R with the lowering of blood glucose level.

The present invention showed for the first time that GHS-R antagonist both suppressed lipid metabolism and lowered blood glucose level.

To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by person of ordinary skill. As stated in *In re Oelrich:*

> Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. See *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981)

Therefore, in order to conclude by the logic of inherency that GHS-R antagonist lowers blood glucose level based on the disclosure of Anderson, the examiner is required to show that one of ordinary skill in the art who reads Anderson will recognizes that GHS-R antagonist lowers blood glucose level. The Examiner has failed to meet this burden.

In view of the above, withdrawal of the rejection of independent claim 4 under 35 U.S.C. 102(b) is respectfully requested. As claim 10 is dependent on independent claim 4, withdrawal of the rejection of claim 10 under 35 U.S.C. 102(b), is also respectfully requested.

Claims 7 to 9, 11 to 13 have been canceled without prejudice by way of this Response, therefore, the outstanding rejections to claims 7 to 9, 11 and 13 are moot.

CONCLUSION

In view of the amendments set forth herein and remarks above, Applicants respectfully submit that the pending claims are allowable, and solicit the issuance of a notice to such effect. If a telephone interview is deemed to be helpful to expedite the prosecution of the subject application, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number provided.

Respectfully submitted,

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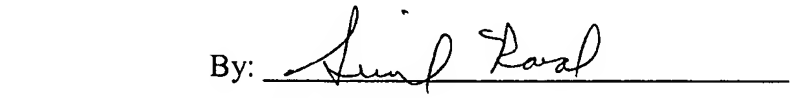
By: 

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